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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,114	03/22/2001	Michael L. Boyer II	8932-208-999	2083
20582	7590	05/18/2004	EXAMINER	
JONES DAY			HAMILTON, LALITA M	
51 Louisiana Aveue, N.W			ART UNIT	
WASHINGTON, DC 20001-2113			PAPER NUMBER	

3624

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,114

Applicant(s)

BOYER ET AL.

Examiner

Lalita M Hamilton

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NW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on amendment filed on February 17, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Summary

On October 16, 2003, an Office Action was sent to the Applicant rejecting claims 1-54 and 56-78. On February 17, 2004, the Applicant responded by amending claims 1-5, 7-19, 21-25, 27-38, 40-44, 46, 52, 56, 62, 70-71, and 77.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 77-78 are rejected under 35 U.S.C. 102(a) as being anticipated by Boyce (5,899,939), as set forth in the previous Office Action, paper no.13.

With regard to the amendment to claim 77, Boyce discloses an innermost ring-shaped member having an outer diameter, the innermost ring-shaped member having an inner diameter, the inner diameter being larger than the outer diameter so that the innermost ring-shaped member is received within the outermost ring-shaped member (see fig.3a and 4 and col.8, lines 1-15 and col.4, lines 50-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-54, 58-59, 61, 67-68 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce in view of McIntyre (4,950,296), as set forth in the previous Office Action.

With regard to the amendment to claims 1 and 21, Boyce discloses the invention substantially as claimed; however, Boyce does not disclose each member being formed from a different region in the body. McIntyre teaches a bone implant comprising bone from a different region in the body (col.3, lines 5-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate each member being formed from a different region in the body, as alternative sources of bone that may be used for the device depending on where the implant is needed.

Claims 56-57, 60, 62-66, 69-70, and 74-76 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boyce, as set forth in the previous Office Action.

Response to Arguments

Applicant's arguments filed February 17, 2004 have been fully considered but they are not persuasive. With regard to independent claim 1, the Applicant has argued that there is no suggestion in Boyce for an implant comprising a body having an inner and outer member....., as claimed in claim 1. In response, Boyce discloses inner and outer members (fig.2: 22 and 23), the inner and outer members resembling at least a portion of a tubular member (fig.2—"at least a portion" of a tubular member is very broad and may include the smallest portion of a tubular member, thus the shape shown in fig.2 may be interpreted as reading onto the limitation substantially as claimed), and

the exterior surface of each inner member contacting no more than one other outer member (fig.2: 22 and 23).

The Applicant argues that there is no disclosure of each member being formed of a bone from a difference region of the body. In response, the rejection has been changed to include McIntyre (see above).

With regard to independent claim 21, the Applicant has argued that Boyce does not disclose a plurality of substantially tubular members or members formed from bone from a different region in the body. In response, Boyce discloses a plurality of substantially tubular members that may be formed from the method disclosed by Boyce (fig.3: 31). Please reference the above response pertaining to the bone from a different region in the body.

With regard to independent claim 40, the Applicant has argued that Boyce does not disclose a plurality of members having a shape substantially resembling a portion of a tubular member each defining a hole, and a core sized and configured to fit within the innermost members. In response, Boyce discloses the plurality of members having a shape substantially resembling a portion of a tubular member (see above response) each defining a hole, and a core sized and configured to fit within the innermost members (col.4, lines 50-65 and col.6, lines 1-20).

With regard to claim 41, the Applicant has argued that Boyce does not disclose an implant comprising two layers of bone components coupled to each other, wherein the implant is formed from at least two different bones selected from the group comprising femur, tibia, humerus, fibula, ulna, and radius and that McIntyre does not

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rectify the failings of Boyce. In response, Boyce disclose two layers of bone components coupled to each (i.e. joined or united together) (fig.2: 22 and 23), but is silent as to the bones being from different regions of the body. McIntyre teaches a bone implant having different types of bone (col.2, lines 52-65 and col.3, lines 15-16). The motivation to combine is the fact that Boyce discloses alternating layers of bone to be used as an implant, but is silent as to the bone coming from different portions of the body, and McIntyre teaches that a bone implant may be made utilizing bone from different areas of the body.

With regard to independent claim 56, the Applicant argues that Boyce does not disclose an implant comprising two annular members and at least one inner annular member, wherein the outer annular members are coupled together to define a central opening for receiving at least one inner member. In response, Boyce discloses this limitation (fig.3a and 4 and col.4, lines 50-65 and col.6, lines 1-20).

With regard to independent claim 77, please reference the rejection above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LMH

RICHARD WEISBERGER
PRIMARY EXAMINER

